K091767
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510(k) SUMMARY

Submitted by:

Brenda Davis
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 West Morgan Street
Spencer, IN 47460
June 15, 2009

OCT - 9 2009

Device:

Trade Name: 3 Way Silicone Foley Balloon Catheter

Proposed Classification Name: Urological catheter and accessories
21 CFR Part 876.5130

Product Code and Class: EZL. Class II

Predicate Devices:

The 3 Way Silicone Foley Balloon Catheter is intended to be used to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder, but may also be accomplished by suprapubic placement or Nephrostomy. The 3 Way Silicone Foley Balloon Catheter is similar with respect to indications for use and technology to existing predicate devices: COOK- Silicone Foley Catheter (510(k) No. 951106), C.R. Bard - Bardex® All Silicone 3-Way Foley (510(k) No. 002868), Well Lead - All Silicone Foley Catheters (510(k) No. 082815), Sewoon Medical Co., LTD - All-Silicone Foley Balloon Catheter (510(k) No. 013276), Rochester Medical Corp.- Two-Way Radiopaque Foley Catheter (510(k) No. 981612), C.R. Bard - Bardex® Lubri-Sil® 3-Way Foley Catheter (510(k) No. 070558). Please refer to **Attachment C** for marketing and FDA information regarding the predicate devices.

Device Description:

The 3 Way Silicone Foley Balloon Catheter is composed of a silicone tube with an imbedded radiopaque blue stripe, a silicone balloon and polyvinylchloride valve. The tube has three lumens, one lumen for urinary drainage which is to be connected to urine collection container, one lumen with two-way valve for inflation/deflation of Foley balloon and one lumen for irrigation of bladder. Catheter is available in 16, 18, 20, 22, 24, 26 French with 30 cc balloon. Catheter is available in open or closed end. Open end allows for use of wire guide (Wire Guide available separate). The 3 Way Silicone Foley Balloon Catheter is intended to be used to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder, but may also be accomplished by suprapubic placement or Nephrostomy.

The devices are provided sterile and are intended for one time use.

Indications for Use:

Used to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder, but may also be accomplished by suprapubic placement or by Nephrostomy.

Substantial Equivalence:

The 3 Way Silicone Foley Balloon Catheter is comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data:

Biocompatibility, sterility and performance testing were performed in accordance to Food and Drug Administration guidances and recognized international standards. Testing data and information is included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT - 9 2009

Ms. Brenda Davis
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 West Morgan Street
SPENCER IN 47460

Re: K091767
Trade Name: 3 Way Silicone Foley Balloon Catheter
Regulation Number: 21 CFR§876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: September 22, 2009
Received: September 24, 2009

Dear Ms. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091767

Device Name: 3 Way Silicone Foley Balloon Catheter

Indications for Use: Used to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder, but may also be accomplished by suprapubic placement or by Nephrostomy.

Prescription Use?___X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091767